

**REMARKS**

**I. STATUS OF THE CLAIMS**

Claims 3, 5, and 44-55 and 59-64 are pending. Claims 1-2, 4, 6-43, and 56-58 are canceled without prejudice or disclaimer. Applicants reserve the right to file one or more continuing applications to the canceled subject matter. Applicants have added claims 61-64.

Applicants have amended claim 3 by deleting the embodiment that had been previously recited in subsection “d (ii)” without prejudice or disclaimer.

Applicants have amended claim 59 to clarify that the claimed progeny plant is obtained from the plant that is grown from the method of step (2) of claim 3, since claim 3 is itself drawn to a method, and not to a “plant” composition *per se*. Applicants also have amended claim 59 to qualify the desired polynucleotide as “consist[ing] essentially of (i) a nucleic acid sequence that is native to the selected plant, native to a plant from the same species as the selected plant, or native to a plant that is sexually interfertile with said selected plant, wherein (ii) the desired polynucleotide does not contain foreign DNA that is not from the selected plant species or a plant that is sexually compatible with the selected plant species.” Written description support for this amendment is found at paragraphs [0029] and [0031] of the originally-filed application.

Applicants have added independent claim 61, which is essentially the method of claim 3 further comprising the step of producing a progeny plant from the transformed parent plant. In this respect, claim 61 is fully supported by the originally-filed specification and claims 1 and 59.

Claim 62 is added to qualify the desired polynucleotide of the progeny plant as being “native” as indicated in the now-amended claim 59.

Claim 63 is added as an independent claim that is identical to claim 3 except Applicants recite the specific sequence, “SEQ ID NO: 49,” instead of the SEQ ID NO: 93 consensus sequence. SEQ ID NO: 49 is found in Table 2 of the specification.

Claim 64 is added and is drawn to a progeny plant of the claim 63 plant wherein the desired polynucleotide is qualified as indicated in the presently amended claim 59.

Since these changes do not introduce any new matter, Applicants respectfully request the entry of these amendments into the record.

## **II. INTERVIEW SUMMARY WITH EXAMINER FOX**

Applicants take this opportunity to thank Examiner David Fox for extending to Applicants' representative, Dr. Caius Rommens, and the undersigned the courtesy of an in-office personal interview on August 26<sup>th</sup>. Applicants appreciate Examiner Fox's guidance and constructive feedback during those discussions and in good faith believe that this present communication takes into account that helpful dialogue.

To that end, Applicants believe they reached agreement with Examiner Fox as to their amendment to claim 59 to qualify the desired polynucleotide in "native" terms as indicated in the body of claim 59, and as supported by the written description where indicated.

Applicants also have deleted the "point mutation" language from claim 3.

Applicants have added claim 63 which is a method identical to claim 3 except it recites the use of a SEQ ID NO: 93 point mutation border sequence denoted by SEQ ID NO: 49. SEQ ID NO: 49 contains a "G" nucleotide, instead of a "T," at the fifth nucleotide position of SEQ ID NO: 93. At the interview, Applicants understood Examiner Fox to agree that a point mutation border variant could be so claimed without objection.

Applicants also understood that Examiner Fox to agree with Dr. Rommens and the report set forth in his Rule 132 Declaration that border sequences that comply with the SEQ ID NO: 93 consensus sequence were functional. That is, Exhibit B of Dr. Rommens' Declaration relates that every successful transformation event occurred with plants that had been transformed with a cassette containing a SEQ ID NO: 93-compliant sequence. Applicants understood from the interview that Examiner Fox agreed that the Declaration data corroborated Applicants' originally-filed disclosure concerning the functionality of SEQ ID NO: 93-conforming nucleotide border sequences and that the recitation of an enzymatic cleavage function in the method claims was therefore unnecessary.

Applicants again thank Examiner Fox for his diligent attention to this matter and believe that they have addressed his concerns and acted on his constructive input in good faith to advance the prosecution of this case.

### III. WRITTEN DESCRIPTION

Claims 3, 5, 44-55, and 58-60 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. According to the Office, claim 3 and its dependents, “do not particularly recite the function associated with the [SEQ ID NO: 93] sequence.” Office Action at page 3. Specifically, claim 3 “recites ‘an enzyme’ rather than ‘a virD2 enzyme’.” *Id.* The Office further asserts that “[m]ore importantly, Applicant has failed to demonstrate that the claimed 17 base pair-long consensus sequence [of SEQ ID NO: 93] is necessary and sufficient for the claimed function of ‘promot[ing] and facilitate[ing] integration of the desired polynucleotide into the plant genome’.” Office Action at page 3. The Office relies on the co-inventor’s own paper, Rommens *et al.*, “Plant-derived transfer DNAs,” *Plant Physiol.* 139: 1338-49, 2005, to say that “even the 24 base pair-long consensus border . . . was not consistently associated with integrative function in almost half of the sequences evaluated.” *Id.* In short, Applicants have “not demonstrated that the conserved sequence, *i.e.*, SEQ ID NO: 93, is correlated with function.”

At the outset, Applicants believe they and Examiner Fox agreed during the August 26<sup>th</sup> interview that the evidence submitted in Dr. Rommens’ Declaration (submitted herewith under 37 C.F.R. 1.132), makes clear that SEQ ID NO: 93-conforming sequences are functional. Accordingly, with respect to the Rommens (2005) paper, Applicants respectfully point out that, like in Exhibit B of the Declaration, *all* of the sequences that they reported in that paper, which had led to functional integration of the desired polynucleotide, comported with the SEQ ID NO: 93 consensus sequence. For this reason, and as shall be explained in detail below, Applicants respectfully believe it is unnecessary to amend any claim to reflect that the SEQ ID NO: 93 consensus sequence is cleaved by an *Agrobacterium* enzyme.

The Declarant, Dr. Rommens – a present co-inventor and co-author of the 2005 paper – corroborates that a variety of plants were successfully transformed using “P-DNA” border sequences that complied with the ANGATNTATN<sub>6</sub>GT consensus of SEQ ID NO: 93. Dr. Rommens highlights that each of the conserved nucleotides of that consensus (A-GAT-TAT-----GT) is conserved in all of the border sequences that were present in the P-DNA constructs that successfully transformed the denoted plants. The conserved residues are shown in highlighting and denoted as “functional.” It was for this reason that Applicants stated in their application that “the present invention encompasses any border-like sequence that has the nucleic acid sequence structure of SEQ ID NO. 93: ANGATNTATN<sub>6</sub>GT (SEQ ID NO. 93), where ‘N’ is any

nucleotide, such as those represented by 'A,' 'G,' 'C,' or 'T.' This sequence represents the consensus sequence of border-like nucleic acids identified by the present invention." See paragraph [0218] of the originally-filed application. Indeed, SEQ ID NOs: 41, 42, 43, 44, 45, 46, 47, 48, 50, 52, 53, 54, and 55, as depicted in Table 2 of the application, all comport exactly with the SEQ ID NO: 93 consensus, and are representative of border sequences that Dr. Rommens showed, and has since showed, are functional border sequences – by virtue of the fact that in all cases the treated plant cells or explants were subsequently successfully transformed when those border sequences were engineered into the transformation construct.

Thus, Rommens (2005) corroborates Applicants disclosure, as emphasized in the accompanying Declaration, that the use of a SEQ ID NO: 93-conforming plant border sequence is correlated with successful transformation function. Applicants therefore have "demonstrated that the conserved sequence, *i.e.*, SEQ ID NO: 93, is correlated with function" and hence respectfully request that the Office withdraw this written description requirement.

#### **IV. ENABLEMENT**

Claims 3, 5, 44-55, and 58-60 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement. Office Action at page 4. The Office "maintains that the claims remain broader than the exemplified consensus sequence." The claims do "not reasonably provide enablement for claims broadly drawn to the use of border sequences comprising SEQ ID NO: 93 or a multitude of 'point mutations' thereof." Office Action at pages 4-5.

Purely in a good faith effort to move this case toward allowance, and without acquiescing to the Office's point of view, Applicants have deleted the point mutation language from the claims. Accordingly, Applicants believe this rejection is moot.

#### **V. ANTICIPATION**

Claim 59 is rejected under 35 U.S.C. § 102(e) as allegedly anticipated by United States Patent No. 6,750,379 ("McElroy"). Office Action at page 6. According to the Office, the plant border sequences in Applicants' transformation cassette "are partially or completely cleaved from the desired polynucleotide before the integration of the latter into the plant genome." *Id.* "Thus, the initially transformed plant or any progeny plant therefrom would be

indistinguishable from any transformed plant containing a 'desired polynucleotide' and not flanked by T-DNA borders, including the transformed plant taught by McElroy." *Id.*

Applicants respectfully assert that McElroy does not teach transforming a plant with a plant with a desired polynucleotide that consists essentially of "(i) a nucleic acid sequence that is native to the selected plant, native to a plant from the same species as the selected plant, or native to a plant that is sexually interfertile with said selected plant, wherein (ii) the desired polynucleotide does not contain foreign DNA that is not from the selected plant species or a plant that is sexually compatible with the selected plant species" as presently recited in claim 59.

McElroy's own experiments show that more than just the "desired polynucleotide" is integrated, or manipulated to delete undesirable sequences. Please see the results at the end of Example 1 (col. 67, lines 15-33). There, McElroy explains that the "data also showed that each phosphinothricin sensitive plant still contained transgene DNA corresponding to the partial bar gene copy, the Bt gene, and the amp gene." These ancillary sequences – along with the required direct repeat sequences – are integrated into the plant genome. McElroy does not teach a method that does not employ a T-DNA border sequence or a sequence that comports with the SEQ ID NO: 93 consensus sequence, as claimed, or a method that integrates only native plant sequences into the plant genome. Applicants respectfully assert therefore that McElroy does not teach each and every element of the invention claimed in claim 59 and therefore does not anticipate the subject matter of claim 59.

**CONCLUSION**

Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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**The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.**